

REMARKS/ARGUMENTS

1. Remarks on the amendment

Claims 11 and 15 have been amended to more specifically define Applicant's claimed invention. Antecedent basis of the amendment of Claim 1 can be found in Claim 15, and page 20, lines 20-25, page 30, lines 1-7 and Examples 4-14 of the Specification as filed.

Applicant submits no new matter is introduced by the amendment.

2. Response to the Rejection under 35 USC §103(a)

Claims 11-16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pearlman et al. (WO/9918800). This rejection is respectfully traversed.

Applicant submits that nothing in the art of record teaches or suggests the subject matter defined by the amended independent Claim 11.

More specifically, as positively recited in the amended independent Claim 11, the instant dermatological composition for topically treating dermatological conditions comprising transient acantholytic dermatitis, acne miliaris necrotica, acne varioliformis, perioral dermatitis, acneiform eruptions, acne vulgaris, or seborrheic dermatitis, said composition consisting of an avermectin compound in a concentration from about 0.05% to about 0.1% (w/v) in a lotion consisting of glycerin, hydrogenated polyisobutene, cetearyl alcohol, polyoxyethylene ether of cetyl and stearyl alcohol, macadamia nut oil, dimethicone, tocopheryl acetate, stearoxytrimethylsilane, stearyl alcohol, panthenol, farnesol, benzyl alcohol, phenoxyethanol, acrylates/C10-30 alkyl acrylate crosspolymer, sodium hydroxide, citric acid, and water; said composition not causing skin irritation of patients suffering from said dermatological conditions upon repetitive daily use.

Therefore, the instant composition is free of chemical components that may cause skin irritation, such as parabens, sodium lauryl sulfate, and quaternium 15. Moreover, as a composite of its chemical components, inclusive both active ingredient and the medium, the instant composition possesses a property of not causing skin irritation upon repetitive daily use, particularly with those suffering from the defined dermatological conditions.

In the instant Office Action, the Examiner states that Pearlman et al. does not explicitly disclose Cetaphil® moisturizing lotion as the pediculocide or explicitly disclose the concentration of ivermectin from about 0.05 to about 0.1% or 0.075%; however, it would have been obvious to one skilled in the art to substitute the Cetaphil® moisturizing lotion for the Cetaphil® Cleanser as both products are produced by the same laboratories and Pearlman et al. teaches of the use of cleansers and lotions/moisturizers interchangeably as a pediculostatic agent.

Moreover, the Examiner further states that it would have been obvious to one skilled in the art to include an active agent (i.e., ivermectin) in a concentration from about 0.1%, etc. in combination with Cetaphil® Cleanser or Cetaphil® moisturizing lotion, as Pearlman et al. teaches of the concentration of from about 0.25% to about 2.5% where concentration of from about 0.25% of Pearlman et al. encompasses the concentration of from about 0.1% and from about 0.075%.

Applicant strongly disagrees and respectfully points out that the Examiner's argument is flawed for the following reasons.

First, Applicant maintains that Pearlman et al.'s opposite teaching does not render the composition and the technical advantages of the present invention obvious.

As disclosed in the present application, the instant composition contains a very low effective concentration of the active component, namely from about 0.05% to about 0.1% (w/v) of an avermectin compound. As demonstrated extensively by

examples, at this very low concentration of the active component the instant composition is clinically effective, and at the same time it does not cause side effect and can be used for daily treatment for extended period of time.

On the other hand, the medium of the instant composition is particularly suitable for topical treatment of transient acantholytic dermatitis, acne miliaris necrotica, acne varioliformis, perioral dermatitis, acneiform eruptions, acne vulgaris, or seborrheic dermatitis. As provided previously, Cetaphil® moisturizing lotion is non-comedogenic and does not contain fragrance, lanolins or parabens that are known cause skin irritation.

It must be understood that the subject dermatological conditions require repetitive exposure of the affected skin with the topical composition for extended period of time. As such, if any components or combinations thereof in the composition may cause undesired reaction of the skin during the treatment, the topical treatment would not be successful.

The present inventor has discovered through clinical trials that the combination of very low concentration of ivermectin with the specific medium as defined is particularly effective for treating the subject conditions. After daily use of the instant composition for up to several months no skin irritation, or increase of skin sensitivity was found (Examples 4-14). As shown in many examples the instant composition was applied at bed time to ensure overnight exposure of the affected area to the composition. As further disclosed, the instant composition can be applied to very sensitive areas, such as around the eyes or directly on the eyelids without causing irritation, and can be used to effectively treat perioral dermatitis that affect these sensitive areas.

On the contrary, Pearlman et al's teaching is directed to a pediculostatic agent for elimination of head lice with a limited time of skin contact, in which the considerations on suitability and patient safety in treating those suffering from the dermatological conditions as defined in Claim 11 are complete absent.

This can be evidenced by Pearlman et al's following teachings. Pearlman et al teach that commercially available products such as soaps, cleansers, lotions, moisturizers, conditioners and shampoos may be used as pediculostatic agent (page 17, lines 1-5). Pearlman et al further teach that the pediculostatic agent includes commercially available skin cleansers, skin conditioners, personal lubricating jelly, sunscreen, mouthwash, toothpaste, and other products; and the pediculostatic agent also includes commonly available honey, vinegar, mustard, gelatin, yogurt, or other foodstuffs, which may be applied for a period of time sufficient to stun the lice (page 17, lines 11-20).

In the preferred embodiments, Pearlman et al teach BABY MAGIC[®] baby shampoo, SUAVE[®] Baby Care bath soap and CETAPHIL[®] Cleanser (page 17, line 22 to page 18, line 15). All of these products contain chemical components, such as sodium lauryl sulfate, quaternium 15, parabens and fragrance, known to cause skin irritation or contact dermatitis. Therefore, none of the preferred compositions taught by Pearlman et al is designed for prolonged skin exposure, and not suitable for topical treatment for those suffering from the dermatological conditions as defined in the present invention.

With regard to the most preferred embodiment of Pearlman et al, CETAPHIL[®] Cleanser, this product contains methyl paraben, propylparaben and butylparaben, which are known causing skin irritation.

Therefore, Pearlman et al's teaching of compositions containing multiple chemicals that are known causing skin irritation teaches away from the instant composition that requires free of these chemicals and requires not causing skin irritation upon repetitive daily use.

On the other hand, with regard to ivermectin, Pearlman et al. specifically teach that the pediculocides active ingredients can be used at levels effective to achieve their intended results of treating head lice infestations, which are at a concentration from about 0.25% to about 2.5% (see page 6, third paragraph). Therefore, contrary to the instant composition, Pearlman et al's method requires a

substantially higher ivermectin concentration in order to be effective to treat head lice infestations. The lowest ivermectin concentration of about 0.25% in Pearlman et al. is more than double of the highest concentration in the instant composition. Therefore, Pearlman et al clearly teaches away from the present invention.

Moreover, it is apparent that Pearlman et al fail to recognize the desire and advantages of using a very low concentration of ivermectin to avoid clinical side effects in treating those suffering from the dermatological conditions defined in the instant application.

From the above, it is evident that Pearlman et al's teaching is only pertinent to a composition having a pediculostatic property. Pearlman et al. does not teach a composition that is suitable for treating subject clinical conditions without causing problems.

Second, the Examiner considers that Pearlman et al. teach of the use of cleansers and lotions/moisturizers interchangeably as pediculostatic agent, therefore, it would have been obvious to one skilled in the art to substitute the CETAPHIL® moisturizing lotion for the CETAPHIL® Cleanser as both products are produced by the same company (Galderma Laboratories, Inc.).

Applicant points out that according to Pearlman et al's teaching, soaps, cleansers, lotions, moisturizers, conditions, shampoos, personal lubricating jelly, sunscreen, mouthwash, toothpaste, honey, vinegar, mustard, gelatin, yogurt, or other food-stuffs are all suitable as pediculostatic agent. This includes tens of thousands of commercial personal care and food products. Just among lotions and moisturizers, there are hundreds of different commercial products available. Using the Examiner's rationale, all of these can be used interchangeably as pediculostatic agent to stun the lice. However, this is a different field from clinical treatment of dermatological conditions. Based on such a teaching, one skilled in the art would not know what to choose in order to obtain the instant composition for treating dermatological conditions. Even if one would try, one would not be able to obtain

the instant composition without undue experimentations.

On the other hand, Galderma Laboratories, Inc. produces hundreds of different commercial products, and each of them has its own composition, property and utility. Therefore, it is not obvious for one skilled in the art to substitute one product for another simply because the two products are made by the same company.

Applicant further points out, based on the Examiner's rationale, if a cleanser that contains chemicals that are not suitable for treatment of subject dermatological conditions and are excluded from the claimed composition would render the instant composition obvious, then a combination of ivermectin with mustard, yogurt or toothpaste would also render the instant composition obvious. It is apparent such a rationale is not sustainable.

Third, the Examiner states that the intended use of the dermatological composition is not afforded any patentable weight. "The recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 44 USPQ2d 1429(Fed. Cir. 1997).

Applicant submits that this is improper application of the case law. The instant composition is structurally different from Pearlman et al's cleanser and ivermectin combination, therefore, it is novel and is not an old product.

Furthermore, as discussed above in detail, the instant composition is not rendered obvious by Pearlman et al. The reference fails to teach a composition that must possess a property of not causing skin irritation of those suffering from the subject dermatological conditions upon repetitive daily use.

Fourth, the Examiner's construction of the scope of concentration range of the active component is improper. The Examiner recites Titanium Metals Corp. of America vs. Banner, 778 F. 2d 775, 227 USPQ 773 (Fed. Cir. 1985), in which the Court held as proper a rejection of a claim directed to an alloy of "having 0.8%

nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium” as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.

Applicant points out that in Titanium Metals Corp of America vs. Banner, the claimed 0.8% nickel is between 0.75% and 0.9% shown by the reference, and the difference of the claimed nickel from the reference is 6% and 12.5%, respectively. As to the molybdenum, the claimed 0.3% molybdenum is also between 0.25% and 0.31% of molybdenum shown by the reference, and the difference of the claimed molybdenum from the reference is 15% and 3%, respectively. As to titanium, the claimed titanium is 98.8% which is between 99% and 98.75% shown by the reference, and the difference of the claimed titanium from the reference is 2% and 0.05%, respectively.

This is substantially different from the present case.

As discussed above, the lowest ivermectin concentration of about 0.25% in Pearlman et al. is more than double of the highest concentration in the instant composition. More specifically, the lowest concentration of 0.25% in Pearlman et al. is 150% higher than the highest concentration of 0.1% in the instant composition. Therefore, it is improper to construe that “about 0.1%” would overlap with a concentration that is 150% higher; and it is improper to construe a concentration of “about 0.25%” would overlap or encompass a concentration that is less than its 50%.

Furthermore, Pearlman et al also lack of teaching of other components of the instant composition. Applicant submits that in order to apply Titanium Metals Corp of America vs. Banner, one has to address first whether Pearlman et al teach a combination of ivermectin with the specific components of Applicant’s claimed composition defined in Claim 1 and a composition possessing the required property. This has been discussed above and has been shown that Pearlman et al fail to provide a fair teaching in both aspects.

Therefore, Applicant maintains that Applicant's claimed dermatological composition defined in the amended Claim 11 is unobvious in view of the prior art of record.

With regard to Claims 12-16, these claims are dependent upon independent Claim 11. Under the principles of 35 U.S.C. §112, 4th paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, independent Claim 11 is not obvious, as such Claims 12-16 are submitted as being allowable over the art of record.

Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. §103(a).

It is respectfully submitted that Claims 11-16, the pending claims, are now in condition for allowance and such action is respectfully requested.

Applicant's Agent respectfully requests direct telephone communication from the Examiner with a view toward any further action deemed necessary to place the application in final condition for allowance.

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Date of Signature

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